

Docket No: 265.0009 0101

DECLARATION

We, Rekha J. Pasricha and Maria A. Micci, declare that: (1) our respective citizenships and residence/ mailing addresses are indicated below; (2) we have reviewed and understand the contents of the specification identified below, including the claims, as amended by any amendment specifically referred to herein, (3) we believe that we are the original, first, and joint inventors of the subject matter in

**TREATMENT OF DISORDERS BY IMPLANTING STEM CELLS AND/OR PROGENY THEREOF
INTO GASTROINTESTINAL ORGANS**

Filing Date: April 12, 2001

Serial No.: 09/834,110

described and claimed therein and for which a patent is sought; and (4) we hereby acknowledge our duty to disclose to the United States Patent and Trademark Office all information known to us to be material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56.*

We hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate listed below, or §365(a) of any PCT international application which designates at least one country other than the United States of America listed below, and have also identified below any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on the basis of which priority is claimed:

- a. ☒ no such applications have been filed.
b. ☐ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119(a)-(d), §365(a), and/or §365(b)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

* Title 37, Code of Federal Regulations, §1.56 is reproduced on the attached page.

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Serial No. 09/834,110

Confirmation No. 5306

Filing Date: April 12, 2001

Title: TREATMENT OF DISORDERS BY IMPLANTING STEM CELLS AND/OR PROGENY THEREOF INTO GASTROINTESTINAL ORGANS

We hereby claim the benefit under Title 35, United States Code §119(c) of any United States provisional application(s) listed below.

- a. ☐ no such applications have been filed.
b. ☒ such applications have been filed as follows:

PROVISIONAL APPLICATION(S), IF ANY, UNDER 35 USC §119(e)	
APPLICATION NUMBER	DATE OF FILING (day, month, year)
60/196,806	13 April 2000
60/232,301	12 September 2000

We hereby claim the benefit under Title 35, United States Code, §120 of any United States applications or §365(c) of any PCT international application(s) designating the United States of America, listed below.

- a. ☒ no such applications have been filed.
b. ☐ such applications have been filed as follows:

APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

Insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, §112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

The undersigned declare further that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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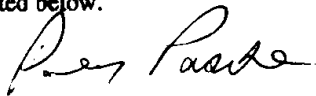
Serial No. 09/834,110

Confirmation No. 5306

Filing Date: April 12, 2001

Title: TREATMENT OF DISORDERS BY IMPLANTING STEM CELLS AND/OR PROGENY THEREOF INTO GASTROINTESTINAL ORGANS

Wherefore, we pray that Letters Patent be granted to us for the invention described and claimed in the specification identified above and we hereby subscribe our names to the foregoing specification, claims, and Declaration, on the date indicated below.



7/25/01

✓ Pankaj J. Pasricha

Date

Citizenship: U.S.A.

Residence: 3315 Oak Links Avenue, Houston, TX 77059

Mailing Address: Same



7/26/01

✓ Maria A. Micci

Date

Citizenship: Italy

Residence: 2880 Morning Pond Lane, Dickinson, TX 77539

Mailing Address: Same

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*Serial No. 09/834,110**Confirmation No. 5306**Filing Date: April 12, 2001**Title: TREATMENT OF DISORDERS BY IMPLANTING STEM CELLS AND/OR PROGENY THEREOF INTO GASTROINTESTINAL ORGANS***§ 1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.